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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/075,404	02/13/2002	Ben F. Johnson	4484C1	8150

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MILA KASAN, PATENT DEPT.
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EXAMINER

NOGUEROLA, ALEXANDER STEPHAN

ART UNIT	PAPER NUMBER
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1753

DATE MAILED: 02/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/075,404

Applicant(s)

JOHNSON ET AL.

Examiner

ALEX NOGUEROLA

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 February 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 22-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 22-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 February 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 02/13/2002.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claim 22 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,372,106 B1 in view of. Knox et al. ("Volume Expansion and Loss of Sample due to Initial Self-heating in Capillary Electrophoresis (CES) Systems," *Chromatographia* vol. 38, no. 5/6, March 1994) ("Knox") and McCormick ("Capillary Zone Electrophoretic Separation of Peptides and Proteins Using Low pH Buffers in Modified Silica Capillaries," *Anal. Chem.* 1988, 60, 2322-2328) (« McCormick »). Claim 1 of U.S. Patent No. 6,372,106 B1 meets all of the limitations of claim 22 of the instant application except that it does not specify a ramp rate, particularly the ramp rate of claim 22. McCormick discloses a capillary electrophoresis method using a ramp rate of 0.70

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V/(cm-s) (capillary length = 110 cm, run voltage = 23kV (from injection voltage of 2kV), and rise time = 300s). See the abstract; Electrophoresis on page 2322; Figure 1; Figure 12; and the second full paragraph in the first column on page 2327. It would have been obvious to one with ordinary skill in the art at the time the invention was made to use a slow ramp rate, particularly within the claimed rate interval, as taught by McCormick in the invention of claim 1 because as taught by McCormick resolution will be improved with a decreased ramp rate. See Figure 12 and the second full paragraph in the first column on page 2327. This is also consistent with Knox who broadly demonstrates how a rapid ramp rate can adversely affect the separation resolution in a capillary electroseparation system. See the abstract.

3. Claim 23 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,372,106 B1 in view of Knox et al. ("Volume Expansion and Loss of Sample due to Initial Self-heating in Capillary Electroseparation (CES) Systems," *Chromatographia* vol. 38, no. 5/6, March 1994) ("Knox") and McCormick ("Capillary Zone Electrophoretic Separation of Peptides and Proteins Using Low pH Buffers in Modified Silica Capillaries," *Anal. Chem.* 1988, 60, 2322-2328) ("McCormick"). Claim 1 of U.S. Patent No. 6,372,106 B1 meets all of the limitations of claim 23 of the instant application except that it does not specify a ramp rate, particularly the ramp rate of claim 23¹. McCormick discloses a capillary electrophoresis method using a ramp rate of 0.70

¹ The specification can always be used as a dictionary to learn the meaning of a term in the patent claim. In re Boylan, 392 F.2d 1017, 157 USPQ 370 (CCPA 1968). Further, those portions of the specification which provide support for the patent claims may also be examined and considered when addressing the issue of whether a claim in the application defines an obvious variation of an invention claimed in the patent. In re Vogel,

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V/(cm-s) (capillary length = 110 cm, run voltage = 23kV (from injection voltage of 2kV), and rise time = 300s). See the abstract; Electrophoresis on page 2322; Figure 1; Figure 12; and the second full paragraph in the first column on page 2327. It would have been obvious to one with ordinary skill in the art at the time the invention was made to use a slow ramp rate, particularly within the claimed rate interval, as taught by McCormick in the invention of claim 1 because as taught by McCormick resolution will be improved with a decreased ramp rate. See the paragraph at the bottom of the second column on page 62 and continue onto page 63. This is also consistent with Knox who broadly demonstrates how a rapid ramp rate can adversely affect the separation resolution in a capillary electroseparation system. See the abstract.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 22 is rejected under 35 U.S.C. 102(b) as being anticipated McCormick (“Capillary Zone Electrophoretic Separation of Peptides and Proteins Using Low pH Buffers in Modified Silica Capillaries,” *Anal. Chem.* 1988, 60, 2322-2328) (« McCormick »). See the abstract; Electrophoresis on page 2322; Figure 1; Figure 12; and the second full paragraph in the first

422 F.2d 438, 441-42, 164 USPQ 619, 622 (CCPA 1970). Thus « separation medium » as used in claim 1 of US 6,372,106 B1 includes a non-crosslinked medium. See column 3, line 65 – column 4, line 2 in US 6,372,106 B1.

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column on page 2327. Note that in the cited passages McCormick discloses an embodiment using a ramp rate of 0.70 V/(cm-s) (capillary length = 110 cm, run voltage = 23kV (from injection voltage of 2kV), and rise time = 300s).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any

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evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 23 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Liu et al. ("Separation of Double- and Single-stranded DNA Restriction Fragments: Capillary Electrophoresis with Polymer Solutions under Alkaline Conditions," *Anal. Chem.* 1999, 71, 1668-1673) ("Liu") in view of Knox et al. ("Volume Expansion and Loss of Sample due to Initial Self-heating in Capillary Electro separation (CES) Systems," *Chromatographia* vol. 38, no. 5/6, March 1994) ("Knox") and McCormick ("Capillary Zone Electrophoretic Separation of Peptides and Proteins Using Low pH Buffers in Modified Silica Capillaries," *Anal. Chem.* 1988, 60, 2322-2328) (« McCormick »). Liu discloses an electrophoresis method in which nucleic acid is separated by differential migration through a buffered solution containing a non-crosslinked polymer under the influence of a run field. See the abstract; Experimental Section on page 1669; and Figure 2. Liu does not mention the ramp rate used; however, as a general principle it was known in the art at the time of the invention that a high ramp rate would adversely affect the separation resolution of a capillary electrophoresis system. See the Knox article, which explains in detail why the ramp rate is important to separation resolution. It was also known at the time of the invention how to evaluate the effect of different ramp rates on separation resolution. See in McCormick the abstract; Electrophoresis on page 2322; Figure 1; Figure 12; and the second full paragraph in the first column on page 2327. It was further known

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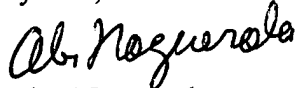
to use a ramp rate of no greater than $5\text{V}/(\text{cm}\cdot\text{s})$. See the passages already cited in McCormick and note that Virtanen discloses a capillary electrophoresis method using a ramp rate of $0.70\text{V}/(\text{cm}\cdot\text{s})$ (capillary length = 110 cm, run voltage = 23kV (from injection voltage of 2kV), and rise time = 300s). Although McCormick does not mention using a non-crosslinked polymer or nucleic acid it should be noted that McCormick does disclose coating the inside of the capillary with polymer and separating proteins. See the abstract and Capillary Modification on page 2322. Thus, in light of the teaching of Knox and McCormick barring a contrary showing, such as unexpected results, Applicants ramp rate of “no greater than $5\text{V}/\text{cm}\cdot\text{s}$ ” is just an optimized ramp rate.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALEX NOGUEROLA whose telephone number is (571) 272-1343. The examiner can normally be reached on M-F 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, NAM NGUYEN can be reached on (571) 272-1342. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Alex Noguerola
Primary Examiner
AU 1753
January 28, 2005